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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,439	06/16/2005	Ennio Ongini	026220-00066	3232
4372	7590	11/29/2007	EXAMINER	
ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			YOUNG, SHAWQUIA	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			11/29/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

## Office Action Summary

**Application No.**

10/537,439

**Applicant(s)**

ONGINI ET AL.

**Examiner**

Shawquia Young

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Claims 1,3, 4 and 6-112 are currently pending in the instant application.

Applicants have cancelled claims 2 and 5 in an amendment filed on September 7, 2007.

### **I. *Response to Arguments***

Applicant's arguments/amendments, filed on September 7, 2007, have overcome the following rejection(s) and objection(s): the rejection of claims 1-10 under 35 USC 112, 1<sup>st</sup> paragraph as failing to comply with the written description requirement; the rejection of claims 1-10 under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite; the objection of claim 1-10 as containing non-elected subject matter; the objection of claims 1,2 and 6 for informalities; the objection of the oath as being defective; and the objection of the specification for not ending in a period. The above rejections and objections are withdrawn.

The Examiner has extended the definition of Y to include the disclosed aromatic linker.

### **II. *Rejection(s)***

#### ***Claim Rejections - 35 USC § 112,1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case,

***The nature of the invention***

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The nature of the invention is drawn to compounds according to claim 1 to be employed as a drug.

***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is necessary in order to satisfy the statute Applicants' claims are drawn to compounds according to claim 1 to be employed as a drug.

Applicants' claim 10 is a broad claim that encompasses the use of the instantly claimed compounds as a drug for the treatment of any disease or disorder. Applicants have failed to state what diseases applicants considered treatable by the claimed compounds in claim 10. It is the state of the prior art that the term "drug" is defined as a substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication.

***The amount of direction present and the presence or absence of working examples***

The only direction or guidance present in the instant specification is minimal. There are no working examples present for the treatment of the diseases encompassed by the broad claim 10 except for the treatment of neuropathic pain.

Test assays and procedure are provided in the specification at pages 26-29 for Writhing test, Paw licking test and Paw pressure test. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims.

***The breadth of the claims***

The breadth of the claims is drawn to compounds according to claim 1 to be employed as a drug.

***The quantity of experimentation needed***

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases out of all conditions would be benefited by the activity of the claimed compounds and would furthermore then have to determine which of the claimed compounds in the instant invention would provide treatment of the diseases.

***The level of the skill in the art***

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* or *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The specification fails to provide sufficient support of the broad use of the claimed compounds of the invention to be employed as a drug. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome, for example, by deleting claim 10.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "the radical of an analgesic drug" is not found previously in claim 1 and it is unclear what "radical" Applicant is referring to. There is insufficient antecedent basis for this limitation in the claim.

Claims 1,3,4 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "R<sub>5</sub> may have the following meanings" found in the variable R<sub>5</sub>; the phrase "OR<sub>A</sub>' R<sub>A</sub> having the following meanings" and the phrase "Q may have one of the following meanings" in claim 1 renders the products indefinite as the phrase "R<sub>5</sub> may have the following meanings" found in the variable R<sub>5</sub>; the phrase "OR<sub>A</sub>' R<sub>A</sub> having the following meanings" and the phrase "Q may have one of the following meanings" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the compounds of the formula I that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the phrase "R<sub>5</sub> may have the following meanings" to read "R<sub>5</sub> is" in claims 1-6; the phrase "R<sub>A</sub> having the following meanings" to read "R<sub>A</sub> is" and the phrase "Q may have one of the following meanings" to read "Q is".

### **III. Conclusion**

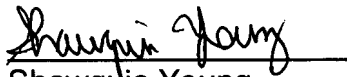


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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